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FJ

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/525,041	03/14/00	SOPPET	D PF178D2

022195
HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE MD 20850

HM22/0907

EXAMINER	
MONSHIPOURI,M	
ART UNIT	**PAPER NUMBER**
1652	7

DATE MAILED: 09/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/525,041	Soppet et al.
Examiner	**Art Unit**
Maryam Monshipouri	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-20 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-20 are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, drawn to isolated polynucleotides encoding a colon specific polypeptide, vctors and host cells comprising said polynucleotides and a method of recombinantly producing a colon specific polypeptide, classified in class 435, subclass 69.1.

II. Claim 9, drawn to a colon specific polypeptide, classified in class 435, subclass 69.1.

III. Claim 10, drawn to an agonist for the polypeptide, classification not determined. This is because the classification for this product depends on the chemical structure of the agonists which has not been clearly defined in the specification.

IV. Claims 11 and 12, drawn to an antagonist and a method of treatment using the antagonist, classified in class 530 subclass 387.1.

V. Claim 13, drawn to a method of treatment comprising administering to the patient DNA encoding the antagonist polypeptide, classified in class 514, subclass 44.

VI. Claim 14, drawn to a method of treatment comprising administering to the patient a therapeutically effective amount of polypeptide, classified in class 435, subclass 69.1.

VII. Claim 15, drawn to a method of treatment comprising administering to the patient an DNA encoding the colon specific polypeptide, classified in class 514, subclass 44.

VIII. Claim 16, drawn to a method of screening compounds to identify antagonists to the polypepitde, classified in class 436, subclass 86.

IX. Claims 17-20, drawn to process for diagnosing a disorder of the colon comprising determining the transcription of a human gene in a sample derived from non-colon tissue, classified in class 436, subclass 94.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptides of invention II may be produced by synthetic methods which is an entirely different method than that of invention I.

Inventions I, III and IV are patentably distinct each from the other. This is because the method of invention I does not utilize any of the product inventions III-IV at any step to reach their final end points. Further, the agonists and antagonists of inventions III-IV may be used for modulation of polypeptide activity which is an entirely different method than any of the method inventions III-IV.

Inventions I, V, VI, VII, VIII and IX are patentably distinct each from the other because each method has different steps and different endpoints. These inventions have acquired a separate status in the art each from the other as evidenced by their separate classification.

Inventions II, III and IV are patentably distinct each from the other because each product has a separate chemical structure and function. These inventions have acquired a separate statu s in the art and require different search strategies.

Inventions II, V, VII and IX are patentably distinct each from the other. This is because the polypeptides of invention II are not being utilized by any method inventions V, VII and IX. Further the polypeptides of invention II may be used for antibody preparation which is an entirely different method the nay of the method inventions V, VII and IX.

Inventions II, VI and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of invention II may be used for antibody preparation which is an entirely different method than any of the method inventions VI and VIII.

Inventions III and IV are patentably distinct because each product has a different chemical structure and function. These inventions have acquired a separate status in the art and require different search strategies.

Inventions III, V, VI, VII, VIII and IX are patentably distinct each from the other. This is because the agonists of invention III are not being utilized by any method inventions V-IX at any step to reach their final end points. Further, the agonists of invention III may be used for signal transduction studies which is an entirely different method than any of the method inventions IV-IX.

Inventions IV, V, VI, VII, VIII and IX are patentably distinct each from the other. This is because the antagonists of invention IV are not being utilized at any step of method inventions VI-IX to reach their final endpoints. Further, the antagonists may be used for signal transduction studies which is an entirely different method than any of the method inventions V-IX.

Inventions V, VI, VII, VIII, and IX are patentably distinct each from the other. This is because each method related to the colon specific polypeptide differently. Further, each method has different steps and different end points. These inventions have acquired a separate status in the art as evidenced by their separate classification.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the Examin should be directed to Maryam Monshipouri, Ph.D. whose telephone number is (703) 308-1083.

The Examiner can normally be reached daily from 8:00 A.M. to 5:00 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. P. Achutamurthy, can be reached at (703) 308-3804. The OFFICIAL fax number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Maryam Monshipouri, Ph.D.

Patent Examiner